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10/551,289	08/21/2006	Debbie Stevens-Wright	B1075.71018US01	1531

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BOSTON, MA 02210-2206

EXAMINER

SCOTT, AMANDA L

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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06/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,289	Applicant(s) STEVENS-WRIGHT, DEBBIE	
	Examiner AMANDA SCOTT	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of amendment filed 04/03/2009. Claims 1 and 3-36 are pending, claim 2 is canceled. An action on the merits is as follows.

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings appear to be hand drawn and some are completely crossed out. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

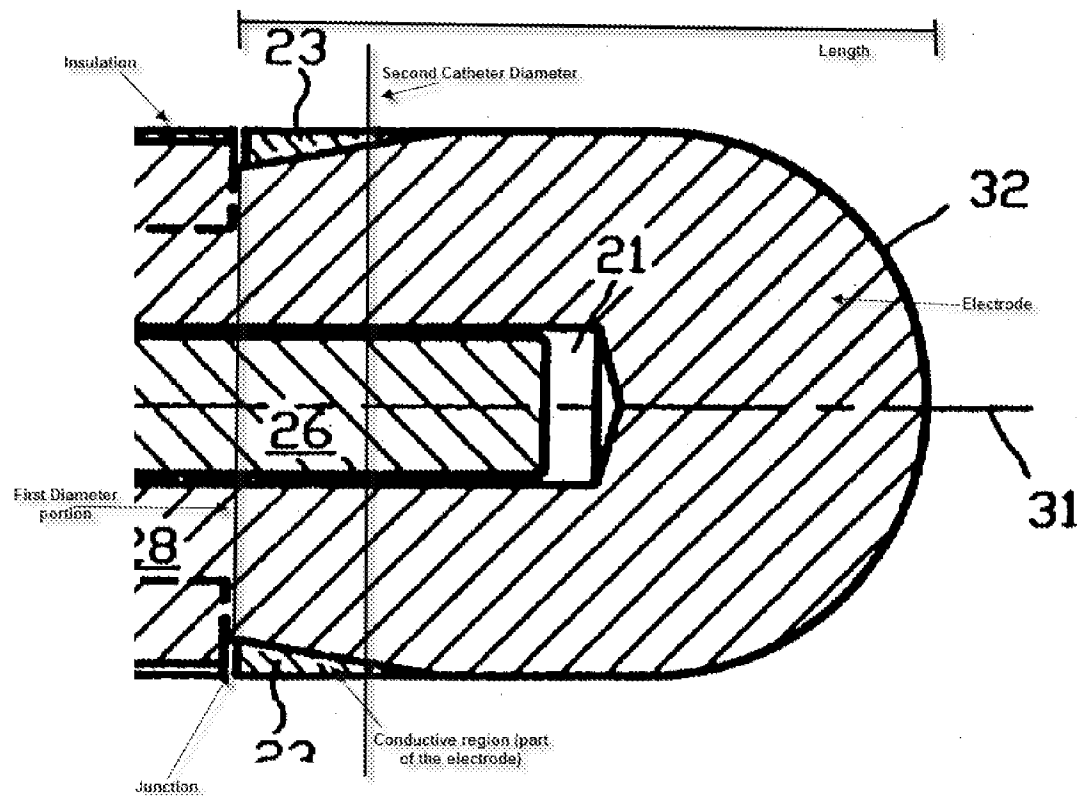
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 3, 5, 7, 9, 12-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Langberg (US 5,230,349).

4. **Regarding claims 1 and 7**, Langberg discloses a catheter comprising: a catheter shaft having a distal end, the distal end of the catheter shaft having an insulating material (24) and a diameter; and an ablation electrode(28) forming a junction

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with the distal end of the shaft, the ablation electrode having an exposed surface; wherein, extending from the junction, the exposed electrode surface has a first diameter portion with a first diameter that is smaller than the diameter of the distal end of the shaft, the first diameter portion forming an angle with the insulating material; and wherein the exposed electrode surface has a second diameter portion with a second diameter that is larger than the first diameter of the first diameter portion, the second diameter portion having a largest diameter that is smaller than a length of the second diameter portion; and wherein the exposed electrode surface further comprises a transition face extending from the first diameter portion to the second diameter portion, the transition face forming an approximately ninety degree angle with the first diameter portion (view figure 4 and figure below) .



5. **Regarding claim 3**, Langberg discloses the catheter according to claim 1, wherein the insulating material, the first diameter portion and the transition face form a recessed region that allows blood to flow across the first diameter portion and the transition face when the electrode is placed in a blood flow (when the catheter is placed in the vascular system blood will flow through the recessed region, view figure 4 and figure above, column 3, lines 32-41)).

6. **Regarding claim 5**, Langberg discloses the catheter according to claim 1, wherein the ablation electrode is a distal tip (28) ablation electrode (column 3, lines 32-41; the catheter is used for ablation).

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7. **Regarding claim 9**, Langberg discloses the catheter according to claim 1, wherein the distance from the insulating material to the transition face along the first diameter portion is less than the diameter of the first diameter portion (view figure above and figure 4).

8. **Regarding claim 12**, Langberg discloses the catheter according to claim 3, wherein the recessed region encircles the ablation electrode (view figure above and figure 4).

9. **Regarding claim 13**, Langberg discloses the catheter according to claim 1, wherein a largest diameter of the electrode is no larger than a diameter of the insulating material forming the first sidewall (view figure 4 and figure above).

10. **Regarding claim 14**, Langberg discloses the catheter according to claim 1, wherein the transition face is parallel to a distal end of the catheter shaft (view figure 4 and figure above).

11. **Regarding claim 15**, Langberg discloses the catheter according to claim 1, wherein the first diameter portion and the insulating material form an angle of approximately ninety degrees (view figure 4 and figure above, the angle is shown as a right angle).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg (US 5,230,349) in view of He (US 2003/0028185).

15. **Regarding claim 4**, Langberg discloses the catheter according to claim 1, but fails to disclose wherein the ablation electrode further comprises a plurality of recessed regions that allow blood to flow across exposed surfaces of the recessed regions when the electrode is placed in a blood flow.

16. However, He discloses an ablation electrode with a plurality of recessed region (view figures 8A and 8B). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode tip of the catheter taught by Langberg with a plurality of recesses as shown by He. Doing so would increase the blood flow to the ablation electrode which will increase the cooling of the tip in order to reduce undesirable charring or coagulation of the surrounding tissue.

17. **Claims 6, 8, 10, 11, 16-18, 35-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg (US 5,230,349).

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18. **Regarding claim 6**, Langberg discloses the catheter according to claim 35, wherein the ablation electrode is a ring ablation electrode (the electrode tip is continuous throughout the catheter which can be a ring electrode).

19. **Regarding claim 8, 10, 11, and 18**, Langberg discloses the catheter according to claim 1, but fails to disclose wherein the distance from the insulating material to the transition face along the first diameter portion is larger than 0.3 millimeters, is approximately 0.9 millimeters and wherein the transition face extends at least 0.3 millimeters toward a center longitudinal axis of the electrode from the exposed surface of the electrode and wherein the ablation electrode is approximately four millimeters in length. However, Langberg does disclose a catheter with an ablation tip electrode having a channel with a transition face. Langberg does not explicitly disclose the lengths or sizes of the transition faces or sidewalls of the junction. Applicant does not give a criticality to any of the specified sizes or distances. It would have been obvious matter of design choice to someone in the catheter ablation art to choose different sizes, depths or distances to the junction, since it is well known in the ablation art to have recessed regions for cooling of the electrode tip during use. In re Rose, 105 USPQ 237 (CCPA 1955). MPEP 2144.04

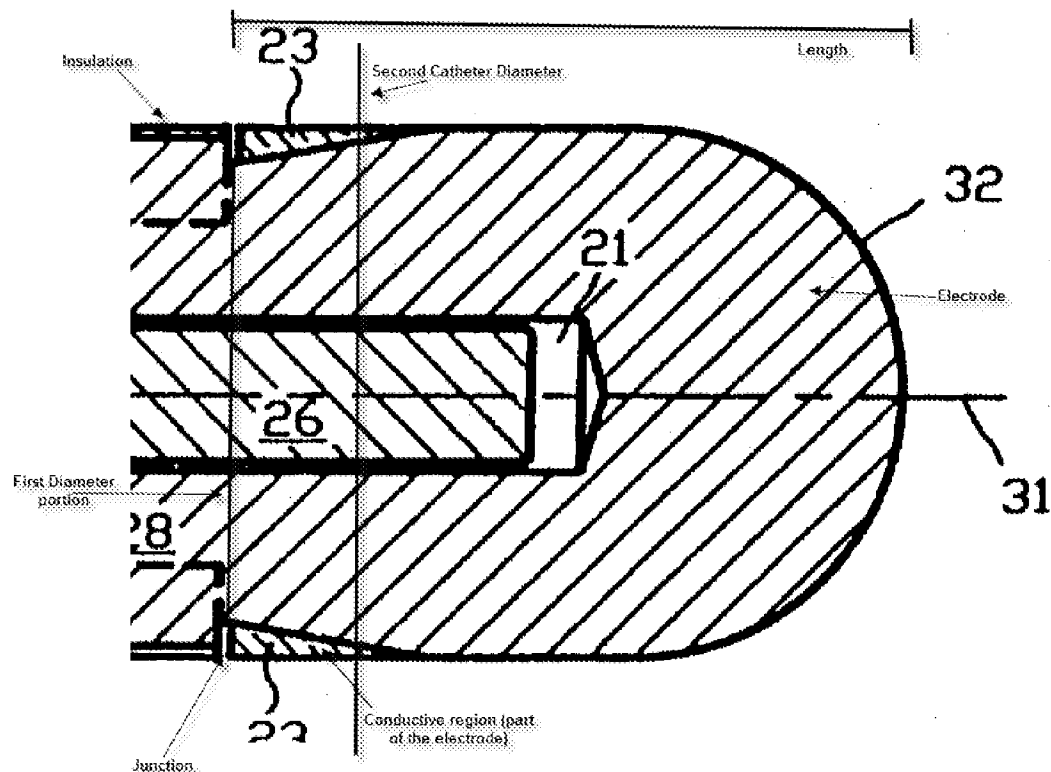
20. **Regarding claims 16 and 17**, Langberg discloses the catheter according to claim 1, but fails to disclose wherein the first diameter portion and the insulating material form an angle of more than or less than ninety degrees. However, changing the angles between the first diameter portion and the insulating material would be a matter of

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obvious design choice in order to improve reduction of the temperature in the electrode tip. In re Rose, 105 USPQ 237 (CCPA 1955). MPEP 2144.04.

21. **Regarding claim 35**, Langberg discloses providing a catheter shaft (24) with an insulating sheath (28); providing an ablation electrode having a first diameter portion with an exposed surface and a second diameter portion with an exposed surface, a transition face between the first and second diameter portions, and the second diameter portion having a length that is larger than a largest diameter of the second diameter portion; and attaching the electrode to the shaft, such that: the first diameter portion of the electrode forms a junction with the shaft, and the first diameter portion has a diameter that is smaller than a diameter of the insulating sheath at the junction of the electrode and the shaft; each of the transition face and the sheath forms a sidewall of a channel and the first diameter portion of the electrode forms a base of the channel the transition face forms an approximately ninety degree angle with the channel base (view figure 4 and figure below).

22. Langberg fails to explicitly disclose a method of manufacture; however, Langberg does disclose all of the claimed parts which are manufactured to be within the scope of the claim. It would have been obvious to one having ordinary skill in the catheter art to take the components as show in figure 4 and manufacture them to have a recessed portion with an exposed electrode surface as well as an insulation sheath. Doing so would allow the user to have a catheter manufactured that can be used within the vasculature of a patient to increase cooling of the tip by having blood or fluid flow through the exposed channel.



23. **Regarding claim 36**, Langberg discloses an ablation electrode tip catheter with a junction/channel but fails to disclose wherein attaching the electrode to the shaft results in the base of channel being at least 0.9 millimeters wide from sidewall to sidewall. Langberg does not explicitly disclose the lengths or sizes of the transition faces or sidewalls of the junction. Applicant does not give a criticality to any of the specified sizes or distances. It would have been obvious matter of design choice to someone in the catheter ablation art to choose different sizes, depths or distances to the junction, since it is well known in the ablation art to have recessed regions for

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cooling of the electrode tip during use. In re Rose, 105 USPQ 237 (CCPA 1955). MPEP 2144.04.

24. **Claims 19-21, 23-34**, are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg (US 5,230,349) in view of Lennox (US 5,122,137).

25. **Regarding claim 19**, Langberg discloses a catheter comprising: a shaft(24) including an electrically insulating material(29); and an ablation electrode(28) forming a junction with the insulating material and having an exposed surface that forms a channel with the insulating material, the insulating material having a diameter at the junction; wherein: a base of the channel comprises a first diameter portion of the exposed electrode surface, and the first diameter portion has a diameter that is smaller than the diameter of the insulating material at the junction; a first sidewall of the channel is comprises, the insulating material at the junction; a second sidewall of the channel comprises a transition face between the first diameter portion and surface-of a second diameter portion of the electrode; and a length of the second diameter portion of the electrode is greater than a diameter of the second diameter portion(view previous figure shown with claim 1 and figure 4), but fails to explicitly disclose that the exposed electrode surface of the first diameter portion is parallel to the second diameter portion of the electrode.

26. However, Lennox discloses an ablation tip catheter that has a portion that creates a right angle and has a first diameter portion that is parallel to a second portion (view figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter disclosed by Langberg with the

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catheter tip disclosed by Lennox. Doing so would create a flat bottomed channel to improve flow through the channel. Modifying the type of electrode tip would be an obvious design choice for someone having ordinary skill in the art. Since applicant does not give any criticality for parallel or slanted channels it is not patentably distinct from the current state of the art of catheter electrode tips.

27. **Regarding claim 20**, Langberg discloses the catheter according to claim 19, wherein the second sidewall forms an angle of less than 120 degrees with the channel base (view figure 4).

28. **Regarding claim 21**, Langberg discloses the catheter according to claim 19, wherein the channel allows blood to flow across the channel base and the second sidewall when the electrode is placed in a blood flow (column 3, lines 32-41; when the catheter is placed in the vascular system blood will flow through the recessed region, view figure 4 and figure above).

29. **Regarding claim 23**, Langberg discloses the catheter according to claim 19, wherein the ablation electrode is a distal tip (28) ablation electrode (column 3, lines 32-41; the catheter is used for ablation).

30. **Regarding claim 24**, Langberg discloses the catheter according to claim 19, wherein the ablation electrode is a ring ablation electrode (the electrode tip is continuous throughout the catheter which can be a ring electrode).

31. **Regarding claim 25**, Langberg discloses the catheter according to claim 19, wherein the second sidewall forms an approximately 90 ninety degree angle with the channel base (view figure 4 and figure above).

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32. **Regarding claim 27**, Langberg discloses the catheter according to claim 19, wherein the distance from the first sidewall to the second sidewall along the base is less than a diameter of the first diameter portion (view figure above (claim 1) and figure 4).

33. **Regarding claim 29**, Langberg discloses the catheter according to claim 19, wherein the channel encircles the ablation electrode (view figure above and figure 4).

34. **Regarding claim 30**, Langberg discloses the catheter according to claim 19, wherein a largest diameter of the electrode is no larger than a diameter of the insulating material forming the first sidewall (view figure 4 and figure above).

35. **Regarding claims 26, 28, and 31**, Langberg discloses the catheter according to claim 19, but fails to disclose the distance from the first sidewall to the second sidewall along the base is more than 0.3 millimeters, the second sidewall extends at least 0.3 millimeters toward a center longitudinal axis of the electrode from an outer surface of the electrode, or the ablation electrode is approximately four millimeters in length.

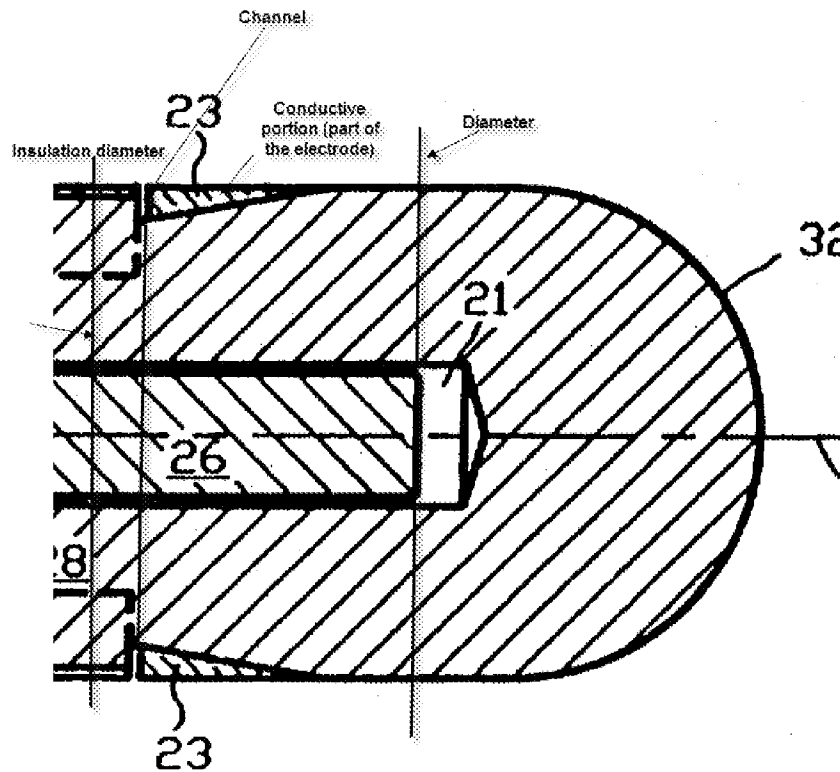
36. However, Langberg does disclose a catheter with an ablation tip electrode having a channel with a transition face. Langberg does not explicitly disclose the lengths or sizes of the transition faces or sidewalls of the junction. Applicant does not give a criticality to any of the specified sizes or distances. It would have been obvious matter of design choice to someone in the catheter ablation art to choose different sizes, depths or distances to the junction, since it is well known in the ablation art to have recessed regions for cooling of the electrode tip during use. In re Rose, 105 USPQ 237 (CCPA 1955). MPEP 2144.04

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37. **Regarding claim 32**, Langberg discloses a catheter comprising: a catheter having an insulating sheath (29); and an ablation electrode(28) non-moveably attached to the insulating sheath, forming a junction with an end of the insulating sheath, and forming a channel with the end of insulating sheath; wherein; the end of the insulating sheath has a diameter; a base of the channel is comprises an exposed electrode surface of the ablation electrode, and a diameter of the ablation electrode along the channel base is smaller than the diameter of the end of the insulating sheath; a first sidewall of the channel is comprises the end of the insulating sheath; a second sidewall of the channel is comprises an exposed electrode surface which extends from the channel base to a portion of the ablation electrode which has a diameter that is larger than the diameter of the channel base portion; and a width of the base of channel is at least one-tenth of the size of the largest diameter of the electrode and less than the smallest diameter of the electrode but fails to disclose the channel base is parallel to the larger diameter portion of the electrode (view figure 4 and figure below). However, Lennox discloses an ablation tip catheter that has a portion that creates a right angle and has a first diameter portion that is parallel to a second portion (view figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter disclosed by Langberg with the catheter tip disclosed by Lennox. Doing so would create a flat bottomed channel to improve flow through the channel. Modifying the type of electrode tip would be an obvious design choice for someone having ordinary skill in the art. Since applicant does not give any criticality for

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parallel or slanted channels it is not patentably distinct from the current state of the art of catheter electrode tips.



38. **Regarding claim 33**, Langberg discloses the catheter according to claim 32, wherein the electrode is a distal tip electrode (view figure above and figure 4).

39. **Regarding claim 34**, Langberg discloses the catheter according to claim 32, wherein the electrode is a ring electrode (view figure 4 and figure above; the electrode tip is continuous throughout the catheter which can be a ring electrode).

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40. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg (US 5,230,349) in view of Lennox (US 5,122,137) in view of He (US 2003/0028185).

41. **Regarding claim 22**, Langberg discloses the catheter according to claim 19, but fails to disclose wherein the ablation electrode further comprises a plurality of channels that allow blood to flow across exposed surfaces of the channels when the electrode is placed in a blood flow.

42. However, He discloses an ablation electrode with a plurality of recessed catheter taught by Langberg with a plurality of recesses as shown by He. Doing so would increase the blood flow to the ablation electrode which will increase the cooling of the tip in order to reduce undesirable charring or coagulation of the surrounding tissue region (view figures 8A and 8B). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode tip of the

Response to Arguments

43. Applicant's arguments with respect to claims 1, 3-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SCOTT whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Thursday, 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739